REMARKS

Claims 10-13 and 41 are pending in the subject application. By this Amendment, applicant has hereinabove canceled claims 11 and 13 without prejudice or disclaimer to applicant's right to pursue the subject matter of these claims in the future. Applicant has also amended claims 10 and 12.

Support for amended claim 10 may be found in the specification, *inter alia*, page 43, lines 10-20. Support for amended claim 12 may be found in the specification, *inter alia*, page 43, lines 10-20. Applicant maintains that claims 10 and 12 as amended do not raise any issue of new matter. Accordingly, applicant requests that this Amendment be entered and considered. Upon entry of this Amendment, claims 10 and 12, as amended, and claim 42 will be pending and under examination.

Rejections Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 10-13 and 42 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to distinctly point out and claim the subject matter which applicant regards as the invention. Specifically, the Examiner alleged claims 10 and 12 are indefinite for use of the term "molecular weight of 62-63kDA." On page 2 of the November 14, 2007 Final Office Action, the Examiner asserted "the molecular weight of a protein depends upon the method used for said determination."

The Examiner further rejected claims 10 and 12 because it was not clear if the "designated 6F11" referred to "the monoclonal antibody" or to the "estrogen receptor alpha."

Additionally, the Examiner rejected claims 10 and 12 as allegedly indefinite "because it is not clear what signal indicates that the agent is an agonist or antagonist of the plasma membrane receptor ER-X." Further, the Examiner asserted claim 10 was allegedly indefinite because "it is not clear if the "contacting the plasma membrane

receptor ER-X with agent" occurs in the presence of a known agonist or if the conditions that would allow the formation of a complex between the plasma membrane receptor ER-X with a known agonist were first determined and said conditions, in the absence of agonist, used when contacting the plasma membrane receptor ER-X with the agent."

In response, but without conceding the correctness of the Examiner's ground of rejection, applicant notes that claims 10 and 12 have been amended to recite "wherein the plasma membrane receptor ER-X has a molecular weight of 62-63kDa as determinable by SDS-PAGE." Applicant maintains the subject specification enables determination method as now recited by amended claims 10 and 12. Specifically, page 33, lines 9-11 recite "The immunoprecipitated proteins were...loaded onto 10% SDS-PAGE gels and separated based upon molecular size." Applicant also notes the Examiner acknowledged on page 3 of the November 14, 2007 Final Office Action, that the subject specification discloses a "species of plasma membrane associated estrogen receptor (ER-X)...having a molecular weight of 62-63kDa determined by SDS-PAGE...". Additionally, claims 10 and 12 have also been amended hereinabove to recite "a murine monoclonal antibody designated 6F11" to more clearly define the antibody used.

Claim 10 has hereinabove been amended to recite the phrase "determine whether an increase in ERK1/2 phosphorylation is generated in step (a), wherein the increase in ERK1/2 phosphorylation indicates that agent is an agonist of the plasma membrane receptor, ER-X." Additionally, claim 12 is similarly amended to recite "determining the increase in ERK1/2 phosphorylation."

Applicant maintain that claims 10 and 12, as amended, point out and distinctly claim the subject matter which applicant regards as the invention and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejections Under 35 U.S.C. §112, First Paragraph, Enablement

The Examiner rejected claims 10-13 and 42 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to enable one skilled in the relevant art to make and/or use the invention. Specifically, the Examiner alleged "the specification, while being enabled for a method for determining whether an agent is an agonist or antagonist of the one species of the plasma membrane associated estrogen receptor (ER-X) disclosed in the specification as having a molecular weight of 62-63kDa determined by SDS-PAGE, wherein the ER-X is isolated by contacting a neocortex tissue lysate from an estrogen receptor-α knockout mouse with a murine monoclonal antibody raised against estrogen receptor alpha (ER-α) designated 6F11 under conditions which permit the formation of a complex between the 6F11 antibody and ER-X; (ii) capturing the complex between the 6F11 antibody and ER-X with an anti-mouse IgG-coated polystyrene magnetizable bead; (iii) precipitating the complex; and (iv) separating ER-X from the complex based upon molecular size, does not reasonably provide enablement for the use of ER-X receptors defined by other means.

The Examiner further rejected claims 10-13 and 42 alleging "the term "molecular weight of 62-63kDA" does not provide sufficient structural and functional information so as to define the ER-X." Further, on page 5 of the November 14, 2007 Final Office Action, the Examiner asserted "the limitation of "obtainable" when defining the receptor by functional limitations leaves open the possibility that is has been obtained by other means."

In response, but without conceding the correctness of the Examiner's ground of rejection, applicant notes claims 10 and 12 have been amended hereinabove to recite "a molecular weight of 62-63kDa as determinable by SDS-PAGE."

Applicant maintains that the receptor, ER-X, as defined by amended

claims 10 and 12 clearly defines the species of the receptor as characterized by a molecular weight of 62-63kDa as determinable by SDS-PAGE and obtainable by the method recited in claims 10 and 12. Importantly, as discussed above, applicant notes the Examiner's acknowledgement on page 3 of the November 14, 2007 Final Office Action that the subject specification is enabling for the species of estrogen receptor "having a molecular of 62-63kDa determinable by SDS-PAGE...". Accordingly, applicant maintains that the specification provides sufficient enablement regarding claimed method including the plasma membrane receptor ER-X as now recited in claims 10 and 12.

Applicant maintains that claims 10 and 12 as amended and claim 42 satisfy the enablement requirement of 35 U.S.C. §112, first paragraph, and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Lastly, the Examiner considers the deposit of biological 6F11 antibody (Novocasta, Vector Laboratories, Burlinghame, CA) to be necessary for the enablement of the current invention because the claims require the availability of the 6F11 antibody in order to fully comply with 37 C.F.R. §§1.803-1.809. According to the Examiner, the current specification does not provide a repeatable method for obtaining 6F11 antibody in the future, but an enabled deposit would satisfy the requirements of 35 U.S.C. §112, first paragraph.

In response, but without conceding the correctness of the Examiner's ground of rejection, applicant is in the process of investigating the availability of the antibody and will appraise the U.S. Patent Office shortly.

Conclusion

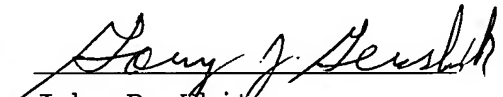
In view of the remarks and arguments made hereinabove, applicant respectfully submits that the grounds of rejection set forth in the November 14, 2007 Final Office Action have been overcome. Applicant therefore respectfully requests that the Examiner reconsider and

withdraw these grounds of rejection, and further request allowance of all claims pending in the subject application, namely, claims 10 and 12, as amended, and claim 42.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed total fee of $1,175.00 (including $770.00 Petition to Revive fee set forth in 37 C.F.R. §1.17(m), and $405.00 R.C.E. fee set forth in 37 C.F.R. §1.17(e)) is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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John P. White Date 7/14/08
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